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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,873	07/21/2003	Pascal Sebastian Bailon	21328 US1	2336

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HOFFMANN-LA ROCHE INC.
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EXAMINER

HEARD, THOMAS SWEENEY

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,873

Applicant(s)

BAILON ET AL.

Examiner

Thomas S Heard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 13th, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) 81-87 and 91-95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-80, 88 & 89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in the action can be found in a prior Office Action.

Claim Rejections - 35 USC § 103

Claims 1-80, 88 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolognesi et al (US 5,464,933), Reddy, K. R., Controlled-Release, Pegylation, Liposomal Formulations: New Mechanisms in the Delivery of Injectable Drugs (2000), The Annals of Pharmacotherapy, Vol. 34, pp 915-923, and Bartley et al (US Patent 5,795,569) as stated in the Office Action of December 14, 2005.

Applicant's arguments filed April 13th, 2005 have been fully considered but they are not persuasive and claims 1-80, 88 and 89 stands rejected under 35 U.S.C. The applicants have argued that none of the cited references in the previous office action teach, suggest, or motivate a skilled artisan to practice the instantly claimed invention of a pegylated T20 polypeptide. This is not found persuasive. Bolognesi et al teaches a pegylated T20 peptide, and reasons for doing so are also provided and stated that they are well known to those of skill in the art, see column 10. The applicant's assert that Bolognesi et al does not teach that the PEG is being attached to the alpha amino group (specification at 13). The alpha amino group is synonymous with N-terminal and therefore Bolognesi et al does teach alpha amino group/N-terminal pegylation.

The applicant's statement that they have found an unexpected result in improved pharmacokinetic characteristics and performance from a pegylated T20 polypeptide is not unforeseen. This is the expected result given that the reason one pegylates peptides to begin with is for improved pharmacokinetic characteristics and performance as taught by Reddy's review article and Bolognesi et al supra.

The applicant's assertion that the examiner selectively chose the advantages from Reddy's review article over the disadvantages is not persuasive in establishing novelty of the pegylated peptide. The applicant's presents the argument from the abstract on page 915 from an incomplete quote of a sentence stating that "not all pegylated-proteins are alike and each requires optimization on a protein by protein basis." Finishing the sentence one finds that Reddy states "not all pegylated-proteins are alike and each requires optimization on a protein by protein basis *to derive maximum clinical benefit.*" This denotes routine optimization for maximum benefit and not discovery of conditions where the invention works at all through trial and error. It is obvious to optimize a parameter when the art recognizes the need for optimization, MPEP 2144.04(VI)(C) and 2144.05(II)(B). Pointing out that Reddy states that "using a PEG that is too large or a protein with too many PEG attachments can result in decreased biological activity" is not a surprising statement but still falls under the purview of routine optimization and the not trial and error of finding a functional pegylated polypeptide. The fact that the examiner did not discuss that pegylation has disadvantages is not a reason for granting novelty to the instantly claimed invention as

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one does not pursue an idea based on the disadvantages real or perceived for the final product. Reddy provides in Table 1 both advantages and disadvantages for pegylating proteins and the advantages far outweigh the disadvantages. In fact, the singular disadvantage is one that can be overcome by routine optimization.

The reasons for pegylation as taught by Bolognesi et al, Bartley et al, and Reddy establish clear motivation to pegylate the T20 polypeptide with a reasonable expectation of success. Bartley et al teaches throughout the patent the use of pegaldehydes for the N-terminal modification of proteins that stimulate megakaryocyte growth and differentiation, and provide numerous references to other proteins that have been modified with pegaldehydes. Reddy teaches the clear advantages of pegylating proteins and demonstrates the use of pegaldehydes in example A on page 920. Bolognesi et al teaches the T20 polypeptide as pegylated and beneficial reasons for pegylating the peptide. The combination of references make the invention prima facie obvious over the prior art. Therefore the rejection is deemed proper and is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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